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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,335	09/28/2001	Jacques Mallet	ST 98036-US-PCT	3243
23117	7590	12/19/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			AKHAVAN, RAMIN	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,335

Applicant(s)

MALLET ET AL.

Examiner

Ramin (Ray) Akhavan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 is/are allowed.
- 6) ☒ Claim(s) 20-27 and 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a response filed 09/16/2005, amending claims 20 and 38.

Claims 20-38 are pending in this application. All objections/rejections not repeated herein are hereby withdrawn. Where applicable, a response to Applicant's arguments is set forth immediately after any objections/rejections set forth herein.

As no new grounds of rejection are set forth, **this action is made FINAL.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 1. Claims 20-27 and 29-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

This is a new ground of rejection insofar as it is applied to material changes made to independent claim 20. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More particularly, the claim is directed to the limitation "[t]he first promoter and the nucleic acid of interest are not from the same gene."¹ It does not appear that the specification provides support for this negative limitation, nor has Applicant pointed to any passage/line providing such support. As such, **the limitation "not on the same gene" constitutes NEW MATTER.**

¹ Previously this rejection was applied to said limitation where the term "on" was utilized instead of the instant term "from". However, the ground of rejection is still applicable and deemed appropriate.

Response to Arguments

Applicant's arguments filed 09/16/2005 have been fully considered but they are not persuasive. The claims are directed to a genus of promoters and nucleic acids of interest that are not from the same gene. As such the claims exclude a broad genus of promoters and nucleic acids. Applicant asserts that the specification provides a list of promoters (p. 6, ll. 6-19) and nucleic acids of interest (pp. 12-16). Further, Applicant asserts that the specification does not require in a specific example that a nucleic acid of interest and a first promoter be from the same gene.

The disclosure provides a list of promoters and genes as Applicant asserts. However, nowhere does the specification provide that the gene of interest and the promoter are necessarily not from the same gene. In fact, where describing what constitutes a gene of interest, the specification includes *any* enzyme, hormone, cytokine, trophic factor, proteins involved in cell cycle, cyclins, protein transporters, proteins involved in metabolism and peptides that are substrates or inhibitors of enzymes. (e.g., pp. 12-14). As such, the single preferred embodiment illustrated in Fig. 1 is not deemed sufficient in supporting the broad generic exclusion to which the amended claim 20 is directed (i.e., excluding any promoter and gene of interest from the same gene). Furthermore, that the specification does not affirmatively require an example where the promoter and the gene of interest are from the same gene *does not* necessarily equate to the specification supporting the converse (i.e., not from the same gene). In other words, lack of a positive assertion does not necessarily equate to support for an exclusionary limitation, especially in light of the broad and inclusive listing of proteins of interest provided in the disclosure. (Id.).

Conclusion

Claim 28 is allowed. Claims 20-27 and 29-38 are rejected. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday-Friday from 8:30-5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636


DAVID GUZO
PRIMARY EXAMINER